



DATE: December 20, 2005 SHEET 1 of 1

**Form PTO-1449 (Modified)**

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. <b>6437.US.C4</b>	SERIAL NO. <b>10/770,290</b>
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)		APPLICANT <b>Y. Qiu et al.</b>	
		FILING DATE <b>February 2, 2004</b>	GROUP <b>1615</b>

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION**

**OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)**

/I.G./	A1	Dulac et al., "Bioequivalence of a New Sustained-Release Formulation of Sodium Valproate, Valproate Modified-Release Granules, Compared with Existing Sustained-Release Formulations After Once- or Twice-Daily Administration", <i>Pharmacotherapy</i> , 25 (1), 35-41, (2005)
	A2	Roberts et al., "Epilim chrono: a multidose, crossover comparison of two formulations of valproate in healthy volunteers", <i>Biopharmaceutics &amp; Drug Disposition</i> , 17 (2), 175-182, (1996)

**EXAMINER**

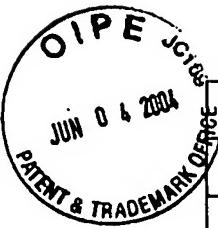
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**EXAMINER:** Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 1 of 2

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**U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
/I.G./	4,369,172	01/18/83	Schor et al.			
	4,699,927	10/18/87	Deboeck			
	4,913,906	04/03/90	Friedman et al			
	4,988,731	01/29/91	Meade			
	5,009,897	04/23/91	Brinker et al			
	5,017,613	05/21/91	Aubert, et al.			
	5,019,398	05/28/91	Daste			
	5,055,306	10/08/91	Barry et al			
	5,169,642	12/08/92	Brinker et al			
	5,185,159	02/09/93	Aubert et al			
✓	5,212,326	05/18/93	Meade			
/I.G./	5,589,191	12/31/96	Ukigaya et al			

**FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)
/I.G./	94/27587	08.12.94	WO			
	00/37055	29.06.00	WO			
	00/45793 A1	08/10/00	WO			
	98/47491	29.10.98	WO			
✓	0 430 287 B2	06/05/91	EP			
/I.G./	0 141 267 B1	08/05/87	EP			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

/I.G./	Bialer et al., Int. J. Pharmaceutics, 20: 53-63 (1984)
/I.G./	Bialer et al., Biopharmaceutics and Drug Disposition, 6: 401-411 (1985)
/I.G./	Bialer et al., Israel J. Med. Sci., 20: 46-49 (1984)
/I.G./	Collins et al., Extended Release Formulations of Anticonvulsant Medications Clinical Pharmacokinetics and Therapeutic Advantages, CNS Drugs 2000 Sept 14 (3): 203-212
/I.G./	Freitag, et al., "Depakote ER in Migraine Prophylaxis", Abstract No. S07.003, Nuerology 54 April 2000 (Suppl 3), page A14.
/I.G./	<u>Physicians' Desk Reference</u> , (Web Version), 2001, Depakote ER, published by The Medical Economics Company
/I.G./	"Metabolism of Antiepileptic Drugs", 143-151, R.H. Levy, Ed. Raven Press, New York (1984)
/I.G./	<u>Physicians' Desk Reference</u> . 54 <sup>th</sup> Edition, 2000, Depakene Capsules, pp. 426-427, published by Medical Economic Company, Inc.
/I.G./	<u>Physicians' Desk Reference</u> . 54 <sup>th</sup> Edition, 2000, Depakote Tablets, pp. 431-437, published by Medical Economic Company, Inc.
/I.G./	Package insert for Depakote® ER dated August 2000
EXAMINER	DATE CONSIDERED

/Isis Ghali/

07/25/2007

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
/I.G./	5,593,690	01/18/83	Schor et al.			
/I.G./	5,593,694	01/14/97	Akiyama et al.			
/I.G./	5,980,913	11/09/99	Ayer et al.			
/I.G./	6,077,542	06/20/00	Sherman			
/I.G./	6,150,410	11/21/00	Engh, et al.			

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	Document Number	Date	Name	Class	Subclass	Translation (Yes No)

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

/I.G./		Abstract of Collins, et al., "Extended Release Formulations of Anticonvulsant Medications Clinical Pharmacokinetics and Therapeutic Advantages", CNS Drugs, New Zealand, 2000, 14/3 (203-212)
/I.G./		Abstract of Bialer, et al., "Criteria to Assess In Vivo Performance and Bioequivalence of Generic Controlled-Release Formulations of Carbamazepine", Epilepsia, United States, 1998, 39/5 (513-519)
/I.G./		Abstract of Chun, et al., "Multiple-dose Evaluation of the Absorption Characteristics of Divalproex Sodium Tablets, a Delayed-Release Preparation of Valproate, in Healthy Volunteers", Clinical Drug Investigation, New Zealand, 1995, 10/1 (40-47)
/I.G./		Abstract of Bressolle, et al., "A Double Weibull Input Function Describes the Complex Absorption of Sustained-Release Oral Sodium Valproate", Journal of Pharmaceutical Sciences, United States, 1994, 83/10 (1461-1464)
/I.G./		Abstract of Hussein, et al., "Pharmacokinetics of Valproate after Multiple-dose Oral and Intravenous Infusion Administration: Gastrointestinal-related Diurnal Variation", Journal of Clinical Pharmacology, United States, 1994, 34/7 (754-759)
/I.G./		Abstract of Wilder, et al., "Gastrointestinal Tolerance of Divalproex Sodium", Neurology, United States, 1983, 33/6 (808-811)
/I.G./		Abstract of Wilder, et al., "Twice-daily Dosing of Valproate with Divalproex", Clinical Pharmacology and Therapeutics, United States, 1983, 34/4 (501-504)
/I.G./		Collins, et al., "Depakote CR: Biopharmaceutical and Pharmacokinetic Studies of a New Formulation for Once Daily Dosing", Neurology, Vol. 50(4), Supplement 4, April 1998, p. A426
/I.G./		Samara, et al., "Bioavailability of a Controlled-Release Formulation of Depakote", No. 3.053, Epilepsia, Vol. 38, Suppl. 8, 1997
/I.G./		Cavanaugh, et al., "Effect of Food on the Bioavailability of a Controlled-Release Formulation of Depakote Under Multiple-Dose Conditions", No. 2.002, Epilepsia, Vol. 38, Suppl. 8, 1997
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